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PATRICIA A. RUBIO

Name (Print)

Signature

In re Application of: Zhu et al.

Serial No.: 09/748,466

Examiner: M. Lamm

Confirmation No.: 3400

Filed: December 26, 2000

Art Unit: 1616

For: NEW USES OF INSULIN AND PANCREATIN

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants submit this Appeal Brief in triplicate as required by 37 C.F.R. §1.192.

A check in the amount of \$165.00 for the required fee pursuant to 37 C.F.R. §§1.192 and 1.17(c) for filing this appeal brief is enclosed. A Notice of Appeal was filed on December 17, 2003. A petition for a two month extension of time is also enclosed.

REAL PARTY IN INTEREST

The real parties in interest are Deguang Zhu and Yao Zhu.

RELATED APPEALS AND INTERFERENCES

Appellants' attorney is not at this time aware of any related appeals and/or interferences which will directly affect, be directly affected by, or otherwise have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 5, 9-14, and 16, shown in the appendix, are on appeal. Claim 6 is canceled by the accompanying amendment.

STATUS OF AMENDMENTS

No amendments prior to the filing of this Appeal Brief have been submitted by Appellant subsequent to the Response to the Final Office Action of October 20, 2003. The October 20, 2003 Amendment was not entered by the Examiner as indicated by the November 19, 2003 Advisory Action.

SUMMARY OF INVENTION

The present invention relates to a method of changing various skin or scalp characteristics or preventing or treating aging skin or scalp by topically applying an effective amount of a composition consisting essentially of insulin to the skin or scalp. The method

includes increasing skin firmness or elasticity, reducing lines or wrinkles of skin, improving age spots or clarity of skin, raising ability of skin or scalp to scavenge oxygen free radicals, raising ability of skin or scalp against UV-induced damage, treating aging of skin or scalp, preventing skin or scalp from aging, treating winter itch, or improving secretion of sebaceous or sweat glands. The insulin can be natural, synthetic, recombinant, human or animal insulin.

ISSUE

Are claims 5 and 9 patentable under 35 U.S.C. §102(b) over Weiner (U.S. Patent No. 5,200,393)?

Are claims 5, 9-14, and 16 patentable under 35 U.S.C. §102(b) over Hinson (U.S. Patent No. 5,145,679).

Because claims 6, 15, and 17 have been canceled, the rejection of claim 6 under 35 U.S.C. §§102(e) and 112, second paragraph, and the objection to claims 15 and 17 are moot.

GROUPING OF CLAIMS

Claims 5, 9-14, and 16 stand or fall together.

ARGUMENT

Claims 5 and 9 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,200,393 (Weiner et al.). The Examiner contends that Weiner teaches using the lipid excipient disclosed therein for delivery of peptides, such as insulin, for both drug and cosmetic uses. See paragraph 10 spanning pages 4 and 5 of the July 21, 2003 Office Action.

Weiner discloses a lipid excipient to be used in pharmaceutical or cosmetic preparations (see abstract of Weiner). The lipid excipient is a non-toxic, non-irritating carrier (*Id.*). The lipid excipient can be administered by the topical, nasal, vaginal, intraocular, buccal, rectal, or intra-aural routes (Weiner, col. 6, lines 41-45).

When used as a cosmetic preparation, the lipid excipient can be applied to the skin alone or in combination with biologically active or other agents (e.g., such as perfumes, paraffins, oils, coloring agents, glycerins) to improve the surface characteristics, e.g., texture and elasticity, of the skin thereby reducing dryness or dehydration, thereby avoiding the onset of dry lines and wrinkles, and other visible signs of aging.

(Weiner, col. 7, lines 9-16).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Weiner does not disclose each and every element of the pending claims. Weiner does not disclose topically administering an insulin formulation to the skin or scalp to change any of the various skin or scalp characteristics recited in the pending claims or to prevent or treat aging skin.

The only insulin formulations disclosed in Weiner are for nasal and mucosal delivery. *See*, for example, the abstract ("For example, the lipid excipient in sprayable or droppable form has special utility in the non-irritating delivery of peptides (e.g., calcitonin and insulin) to the nasal mucosa, due to the ability of the excipient to enhance absorption across nasal membranes") and claim 1 of Weiner.

The only examples of insulin formulations in Weiner are for intranasal or surgically instilled delivery. *See* Examples 4 and 6-8 in Weiner.

Weiner, therefore, does not disclose the topical administration of insulin let alone topical administration of insulin for changing any of the various skin or scalp characteristics recited in the pending claims or to prevent or treat aging skin.

In the July 21, 2003 Office Action, the Examiner refers to column 7, lines 9-16, of Weiner, which discloses that “[w]hen [the lipid excipient] is used as a cosmetic preparation, the lipid excipients can be applied to the skin alone or in combination with biologically active or other agents (e.g., such as perfumes, paraffins, oils, coloring agents, glycerins) to improve the surface characteristics ... of the skin ...” (emphasis added). In other words, the lipid excipient improves the surface characteristics of the skin with or without the biologically active or other agents. This does not suggest that any of the biologically active or other agents included in the cosmetic preparation improves the surface characteristics of the skin. For example, perfumes and coloring agents are both referred to as agents that can be included in the cosmetic preparation, but neither necessarily improves texture, elasticity or wrinkles of skin.

Therefore, Weiner does not disclose or suggest using insulin in a cosmetic preparation. Rather, Weiner emphasizes the use of his lipid excipients for intranasal delivery of insulin as discussed above.

For the foregoing reasons, Weiner fails to anticipate claims 5 and 9.

Claims 5, 9-14, and 16 stand rejected as under 35 U.S.C. §102(b) as anticipated by Hinson (U.S. Patent No. 5,145,679).

Hinson discloses a topical emollient containing a source of glucose and insulin for the treatment of circulation induced *lesions* (Hinson, abstract). The circulation induced lesions, such as skin lesions, ulcers and maladies, are a pathologic result caused by diabetes, phlebitis, or other circulatory problems (Hinson, col. 1, lines 12-35).

In contrast, the method of the presently claimed invention includes applying the composition of the present invention to skin or scalp, not skin lesions, skin ulcers, or skin maladies. Skin lesions, skin ulcers, and skin maladies as defined in Hinson are not encompassed by the definition of skin as used in the present application. For example, the term “wounds”, which includes lesions, is considered separate and distinct from skin at page 6, lines 11-15, of the specification.

Furthermore, Hinson does not provide any motivation for treating physiological changes in skin such as those recited in the pending claims. Rather, Hinson only teaches treating pathological changes in the skin, such as the formation of skin lesions and skin ulcers, with a mixture of insulin and glucose. Hinson also does not provide a reasonable expectation that the compositions of the presently claimed invention would be able to treat physiological changes in skin such as those recited in the pending claims.

For the foregoing reasons, Hinson does not anticipate claims 6, 9-14, and 16.

IV. CONCLUSION

For the foregoing reasons, Weiner and Hinson fail to anticipate the presently claimed invention and the rejections of claims 5, 9-14, and 16 should be reversed by the Board. Such a disposition is earnestly solicited.

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Appendix
Claims at Issue on Appeal
U.S. Serial No. 09/748,466

5. A method of increasing skin firmness and elasticity, reducing lines and wrinkles of skin, improving age spots and clarity of skin, raising ability of skin or scalp to scavenge oxygen free radicals, raising ability of skin or scalp against UV-induced damage, treating aging of skin or scalp, preventing skin or scalp from aging, treating winter itch, or improving secretion of sebaceous and sweat glands comprising:

topically applying an effective amount of a composition consisting essentially of insulin, which can be natural, synthetic, recombinant, human or animal, to the skin or scalp.

9. A method of treating aging of skin or scalp or preventing skin or scalp from aging comprising:

topically applying an effective amount of a composition consisting essentially of insulin, which can be natural, synthetic, recombinant, human or animal, to the skin or scalp.

10. The method of claim 5, wherein the composition consists essentially of at least 2 units of insulin, which can be natural, synthetic, recombinant, human or animal, per 100 g of composition.

11. The method of claim 10, wherein the composition is a solution or emulsion.

12. The method of claim 10, wherein the composition consists essentially of 2 to 20 units of insulin per 100 g of composition.

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13. The method of claim 12, wherein the composition is a solution or emulsion.

14. The method of claim 9, wherein the composition consists essentially of at least 2 units of insulin, which can be natural, synthetic, recombinant, human or animal, per 100 g of composition, wherein the composition is a solution or emulsion.

16. The method of claim 14, wherein the composition consists essentially of 2 to 20 units of insulin per 100 g of composition.